

REMARKS

In a non-final Office Action mailed April 10, 2003, the Examiner in charge of the application rejected pending Claims 5-9, 11-13 and 19-21. Claims 5-9 and 11-13 were rejected for indefiniteness under 35 U.S.C. §112, second paragraph. The pending claims other than Claim 8 were rejected as anticipated by WO200134626-A1(Accession No. AAD5303), Accession No. BC012074 from NCBI. The pending claims were rejected under the same section as being anticipated by Bradley et al. (2001). Claims 5-9 were rejected under 35 U.S.C. §102(a) or (b) as being anticipated by St. Croix et al. (2000).

Each issue raised by the Examiner is considered separately below. In view of the amendments noted above and the arguments below, applicants respectfully request reconsideration of the merits of this patent application.

Status of Supplemental Information Disclosure Statement

The Examiner is asked to note on the record whether a supplemental IDS filed by the Applicants has been considered. The Supplemental IDS was filed on March 4, 2003 and was received by the US PTO on March 10, 2003, but was not mentioned in the Office Action of April 10, 2003.

Clarification on Prior Amendment

The Examiner correctly notes that Claim 11 was amended in the prior response. To avoid any uncertainty, the applicants ask the Examiner to note that fact in the record by including the term “(amended)” in Claim 11 of the prior response. Claim 11 is not presently amended, but rather is here designated as “(previously amended)” in accord with the new amendment practice.

Rejections Under 35 U.S.C. §112, second paragraph

Claims 5-9 and 11-13 were rejected under §112, second paragraph for alleged indefiniteness. With regard to SEQ ID NOS:6, 8, and 10, the Examiner stated “it is not clear if the polynucleotide encodes the polypeptide or not.” The Examiner’s question overlooks an important recitation in the claim. The claim states that the claimed isolated polynucleotide encodes a soluble polypeptide (i.e., lacking a functional transmembrane domain and not membrane-bound) selected from the group consisting of various protective antigen (PA)-binding fragments of certain polynucleotides. To clarify that the encoded polypeptide is soluble, the claims are amended to recite that the claimed polynucleotide encodes “a

polypeptide that consists essentially of a soluble polypeptide selected from" various soluble polypeptides, as well as fusion proteins comprising such soluble polypeptides. The final clause of the claim, which states that the polynucleotide of the claim is unable to encode the polypeptides of SEQ ID NO:6, 8, or 10, makes clear, perhaps redundantly, that the claim does not extend to polynucleotides that encode the full length polypeptides of SEQ ID NO:6, 8, or 10. Rather, in this aspect, the claimed polynucleotides include those that encode soluble PA-binding fragments.

Applicants trust that this clarifies the intent of Claims 5-9 and 11-13, and therefore respectfully request reconsideration.

Priority Date

Applicants respectfully ask the Examiner to maintain the claim to priority of provisional application number 60/251,481, filed 12/05/00 for all that it discloses. Applicants acknowledge that the sequences disclosed in the pending application were not disclosed in the provisional application.

Objection to the Specification

The Examiner objected to the specification for inclusion of an embedded hyperlink. The hyperlink is removed from paragraph [00034] by amendment and the objection is believed cured.

Rejections Under 35 U.S.C. §102

The Examiner maintained a rejection of Claim 5-7, 9, 11-13 and 19-21 for alleged anticipation by WO200134626. The Examiner placed the burden on comparing the applicants' polynucleotides with the polynucleotide of the prior art to show a novel or unobvious difference between the two. The Examiner suggested that it would be appropriate to show that the polynucleotide of the prior art does not possess the same material structural and functional characteristics of the claimed polynucleotide.

Applicants respectfully point out that the Examiner has overlooked that the polynucleotide sequence cited against the claims is not a soluble peptide, but rather encodes a polypeptide having a transmembrane region which corresponds to the twenty-three amino acid long putative transmembrane region of SEQ ID NO:2. (See specification at paragraph [00027]. The cited art does not disclose any fragment of the cited sequence, but rather merely discloses the full length sequence.

In contrast, the applicants point out at paragraph [00035] that soluble fragments that maintain a PA-binding activity are of great interest as these can competitively inhibit anthrax toxin binding to the anthrax toxin receptor. Such fragments are not disclosed in the cited art, and the cited art provides no teaching or suggestion to select and employ the claimed portions of the full-length polynucleotide or polypeptide sequences. Applicants contend that this distinction is a *prima facie* difference in structure. Moreover, this structural difference forms a basis for a functional distinction by applicants' invention over the cited art, especially insofar as none of the cited art identifies the full length polypeptide as relating in any way to a receptor for anthrax toxin and, as such, the prior art provides no direction, motivation or incentive for one to employ a soluble polypeptide that competitively binds up anthrax toxin and prevents binding to the native (cell-bound) anthrax toxin receptor. Nor does the art provide any teaching relating to selection of a polynucleotide encoding such a polypeptide. Again, the prior art simply does not disclose, does not teach, and does not suggest producing the encoded polypeptide in a soluble form. The same holds true for the claimed vectors and host cells that comprise such a polynucleotide.

Appeal now not for functional distinction only

The pending claims are also rejected under §102(a) as being anticipated by Bradley et al. (2001). Applicants have confirmed with the publisher of Nature that the cited article was not released in print until November 8, 2001, subsequent to the filing date. On its face, the article indicates that it was published online after the applicants' filing date. Accordingly, applicants see no basis for maintaining the rejection under §102(a) and ask for further clarification from the Examiner before resorting to a declaration under In re Katz.

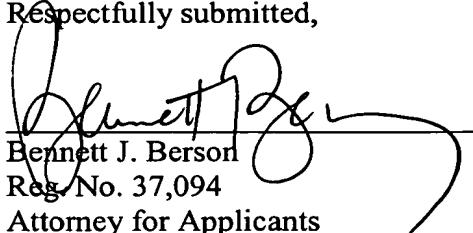
Claims 5-9 were rejected under §102(a) or (b) as being anticipated by St. Croix et al. (2000). For the reasons noted above in connection with the rejection over WO200134626, applicants maintain that the polynucleotides recited in the claims cannot be anticipated by the cited art.

Having responded to each ground of rejection imposed by the Examiner, applicants respectfully request reconsideration of the merits of this patent application.

A petition for an extension of time for one month accompanies this response so the response will be deemed to have been timely filed. Should any additional extension of time be due, please consider this to be a request for the appropriate extension of time and a request to charge the required fee to Deposit Account No. 17-0055. No other fee is believed due, but

should any other fee be due, please consider this to be a request to charge the fee to the same
Deposit Account.

Respectfully submitted,


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